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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,623	05/02/2001	Thomas Dyrberg	4401.214-US	6709

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Reza Green, Esq.
Novo Nordisk of North America, Inc.
Suite 6400
405 Lexington Avenue
New York, NY 10174-6401

EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary	Application N.	Applicant(s)	
	09/847,623	DYRBERG ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8,9 and 11* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 6, 8, 9 and 11 are currently pending.

Claims 6 and 8-9 are under consideration to the extent they read on the elected invention.

Claim 11 is withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

Applicant's election with traverse of AspB25 human insulin in Paper No. 5 (dated 6/30/03), which is asserted to read on claims 6 and 8-10, is acknowledged. The traversal is on the ground(s) that there is no serious burden to examine the entire application on its merits. This is not found persuasive for the reasons provided in the requirement for election of species (paper no. 4) e.g. difference in insulin structure/activity/properties and manufacture and different and separately burdensome manual/computer search for each of these different insulin species.

The requirement is still deemed proper and is therefore made FINAL.

Claim 11 is withdrawn from further consideration as being drawn to a nonelected invention pursuant to 37 CFR 1.142(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter rejection). The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to the phrase "*the in vitro activity* of the insulin analogue less than 7% of *the activity of human insulin*"; to the extent that the "in vitro activity" of the analogue or the "activity of human insulin" is broader than hypoglycemic activity described in the specification (e.g. see specification page 10), the increase in breadth of activities for both insulin and its analog constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 8, the phrase "*the in vitro activity* of the insulin analogue less than 7% of *the activity of human insulin*" is indefinite for lacking metes and bounds regarding the encompassed scope of activities (e.g. physical/chemical/biologic or otherwise) for both insulin and its corresponding analogue that is within the currently claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by Affholter et al. Biochemistry Vol. 29 (33) (1990) pages 7727-7733.

The claimed invention is a pharmaceutical composition comprising AspB25 human insulin wherein:

a. the AspB25 human insulin is asserted to be "a hormonally inactive insulin analogue" (as defined on page 10 of the present specification; and with in vitro activity < than 7% of human insulin: see claim 8) AND

b. the pharmaceutical composition is "for treating or ameliorating type I diabetes" (intended use).

The Affholter et al. reference teaches compositions that comprises Asp B25 human insulin whose compositions are within the scope of the presently claimed invention since:

a. the present claims only require the presence of AspB25 human insulin:

b. AspB25 human insulin analogue is inherently "a hormonally inactive insulin analogue" and "pharmaceutically acceptable"; and

c. intended use limitations (e.g. "pharmaceutical" i.e. for treating or ameliorating type I diabetes) are not afforded patentable weight in compound/composition claims.

Alternatively, if the term "pharmaceutical" is given any patentable weight it is noted that the Affholter et al. reference teaches:

a. that AspB25 human insulin analogues inhibit (e.g. in vitro) Insulin-degrading enzyme (IDE) (e.g. see pages 7729-7730 and figures and tables thereon);

b. " ... IDE appears to be responsible for the initial cleavage of internalized insulin by insulin-responsive cells" (e.g. see pages 7727-8) and

c. "... specific inhibitors of the enzyme are not available ..." (see page 7728, left column) ; with the binding of insulin analogues, facilitating the design of protease-resistant insulin analogues and peptide-based inhibitors of insulin-degrading enzyme (e.g. see pages 7733);

which all (a.-c. above) serves as a reference suggestion (e.g. anticipates) to one of ordinary skill in the art the making of pharmaceutical compositions comprising human AspB25 insulin for in vivo use e.g. for developing IDE inhibitors.

Claims 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by Drejer et al. Diabetes Vol. 40 (Nov. 1991) pages 1488-1495.

The claimed invention is a pharmaceutical composition comprising AspB25 human insulin wherein:

a. the AspB25 human insulin is asserted to be "a hormonally inactive insulin analogue" (as defined on page 10 of the present specification; and with in vitro activity < than 7% of human insulin: see claim 8) AND

b. the composition is "pharmaceutical" e.g. "for treating or ameliorating type I diabetes" (intended use).

The Drejer et al. reference teaches compositions that comprises Asp B25 human insulin whose compositions are within the scope of the presently claimed invention since:

a. the present claims only require the presence of AspB25 human insulin:

b. AspB25 human insulin analogue is inherently "a hormonally inactive insulin analogue" and "pharmaceutically acceptable"; and

c. intended use limitations (e.g. "pharmaceutical" i.e. for treating or ameliorating type I diabetes) are not afforded patentable weight in compound/composition claims. In regard, to item b. above it is noted that the reference explicitly teaches "a hormonally inactive insulin analogue" (e.g. human AspB25 insulin) within the specification definition (e.g. see Tables and figures ; and Abstract teaching binding affinities of 0.05% for Asp B25 human insulin).

Alternatively, if the term "pharmaceutical" if given any patentable weight it is noted that the Drejer et al. reference teaches that the disclosed insulin analogues are "... valuable for in vitro *and in vivo studies*" (e.g. see Abstract; page 1488 right column; page 1494 (especially right column) which suggest (e.g. anticipates) to one of ordinary

skill in the art the making of pharmaceutical compositions comprising human AspB25 insulin for in vivo use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 703-305-7556. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
July 28, 2003